Claims

1. Sustained-release pharmaceutical composition comprising a core of

   (a) Tamsulosin in the form of the base and/or in the form of a pharmaceutically acceptable salt, and
   (b) optionally at least one excipient and
   (c) a coating which contains a combination of polyvinylacetate (PVAC) and polyvinylpyrrolidone (PVP).

2. Pharmaceutical composition according to claim 1, wherein the pharmaceutically acceptable salt is Tamsulosin hydrochloride.

3. Pharmaceutical composition according to claim 1 or 2, which comprises Tamsulosin in an amount of 0.005 to 1.20 wt.%, based on the total weight of the pharmaceutical composition.

4. Pharmaceutical composition according to claim 3, which comprises Tamsulosin in an amount of 0.08 to 0.20 wt.%, based on the total weight of the pharmaceutical composition.

5. Pharmaceutical composition according to claim 4, which is a single dosage form and comprises Tamsulosin in an amount of from 0.025 to 1.2 mg.

6. Pharmaceutical composition according to any one of claims 1 to 5, which is in the form of tablets, capsules, granules or pellets.

7. Pharmaceutical composition according to any one of claims 1 to 6, which comprises the PVAC and PVP in the coating (c) in an amount of 1 to 30 wt%, based on the total weight of the pharmaceutical composition.

8. Pharmaceutical composition according to claim 7, which comprises the PVAC and PVP in the coating (c) in an amount of 2 to 20 wt%, based on the total weight of the pharmaceutical composition.

9. Pharmaceutical composition according to any one of claims 1 to 8, wherein the layer thickness of the coating (c) is in the range of 10 to 50 μm.

10. Pharmaceutical composition according to claim 9, wherein the layer thickness of the coating (c) is in the range of 10 to 40 μm.

11. Pharmaceutical composition according to claim 10, wherein the layer thickness of the coating (c) is in the range of 10 to 25 μm.

12. Pharmaceutical composition according to any one of claims 1 to 11, wherein the weight ratio of polyvinyl acetate to polyvinyl pyrrolidone in the coating (c) ranges from 1.5 : 1 to 14 : 1.

13. Pharmaceutical composition according to claim 12, wherein the weight ratio of polyvinyl acetate to polyvinyl pyrrolidone in the coating (c) ranges from 9 : 1 to 12 : 1.

14. Pharmaceutical composition according to any one of claims 1 to 13, wherein the excipient (b) is an embedding material selected from the group consisting of polyvinyl pyrrolidone and cellulose ethers.

15. Pharmaceutical composition according to claim 14, wherein the embedding material (b) is a cellulose ether.

16. Pharmaceutical composition according to any one of claims 14 to 15, wherein the weight ratio of Tamsulosin to embedding material (b) ranges from 1 : 3 to 1 : 25.

17. Pharmaceutical composition according to claim 16, wherein the weight ratio of Tamsulosin to embedding material (b) ranges from 1 : 4 to 1 : 19.

18. Pharmaceutical composition according to any one of claims 1 to 17, further comprising

one or more non-ionic surfactants selected from the group consisting of alkylglycosides, alkylmaltosides, alkylthioglucosides, polyoxyethylene alkyphenols, polyoxyethylene alkylethers, polyethyleneglycol fatty acid esters, polyethyleneglycol glycerol fatty acid esters, polyoxyethylene-polyoxypropylene block copolymers, polyglyceryl fatty acid esters, polyoxyethylene glycerides, polyoxyethylene vegetable oils, polyoxyethylene hydrogenated vegetable oils and sterols.

19. Pharmaceutical composition according to claim 18, wherein the non-ionic surfactant is a polyoxyethylene sorbitan fatty acid ester.

20. Pharmaceutical composition according to any one of claims 18 to 19, wherein the weight ratio of Tamsulosin to the non-ionic surfactant ranges from 1 : 12 to 1 : 25.

21. Pharmaceutical composition according to claim 20, wherein the weight ratio of Tamsulosin to the non-ionic surfactant ranges from 1 : 16 to 1 : 19.

22. Sustained-release pharmaceutical composition, comprising Tamsulosin in the form of the base and/or in the form of a pharmaceutically acceptable salt, characterized in that the ratio between maximum plasma concentrations of the Tamsulosin determined after administration of said pharmaceutical composition under fasting conditions and under fed conditions according to the $Cmax_{fasting/fed}$-test is less than 1.35.

23. Pharmaceutical composition according to claim 22, wherein the ratio is less than 1.25.

24. Pharmaceutical composition according to claim 22, wherein the ratio is less than 1.2.

25. Pharmaceutical composition according to claim 22, wherein the ratio is equal to or less than 1.15.

26. Process for the manufacture of a pharmaceutical composition according to any one of claims 1 to 25 comprising the steps of

(i) providing Tamsulosin, optionally in combination with at least one excipient (b) and

(ii) applying a coating (c) thereon which contains a combination of polyvinyl acetate and polyvinyl pyrrolidone.

27. Process according to claim 26, comprising the steps of

(i1) providing neutral pellets,

(i2) optionally coating said neutral pellets with a first subcoat,

(i3) coating said pellets of step (i1) or (i2) with a dispersion that contains Tamsulosin,

(i4) optionally coating said pellets of step (i3) with a second subcoat,

(ii1) applying on said pellets of steps (i3) or (i4) a coating which contains a combination of polyvinyl acetate and polyvinyl pyrrolidone, and

(ii2) optionally coating said pellets of step (ii1) with a third subcoat, and

(ii3) optionally coating said pellets of step (ii1) or (ii2) with an overcoat.